

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
Menghang XIA
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RAHWAY, NJ 07065-0907

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference PCT 21421		Date of mailing (day/month/year) 05 SEP 2007
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US04/31820	International filing date (day/month/year) 28 September 2004 (28.09.2004)	Priority date (day/month/year) 02 October 2003 (02.10.2003)
International Patent Classification (IPC) or both national classification and IPC IPC: Please See Continuation Sheet USPC: 435/69.1, 320.1, 325, 514/12, 530/350, 300, 536/23.1		
Applicant MERCK & CO., INC		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

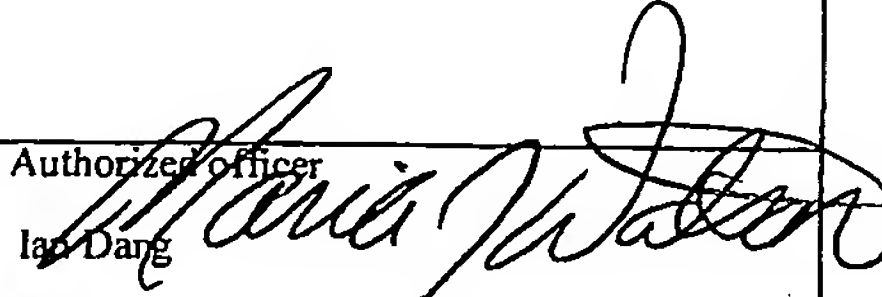
2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 23 July 2007 (23.07.2007)	Authorized officer  Ian Dang Telephone No. (571) 272-1600
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Form PCT/ISA/237 (cover sheet) (April 2005)

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☒ on paper
 - ☒ in electronic form
 - c. time of filing/furnishing
 - ☒ contained in the international application as filed.
 - ☒ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
 - ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
 - ☐ complied with
 - ☒ not complied with for the following reasons:
See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
 - ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-5, 7-15, 41, 42, 46, and 47

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-5, 7-15, 41, 42, 46, and 47</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-5, 7-15, 41, 42, 46, and 47</u>	NO
Industrial applicability (IA)	Claims <u>NONE</u>	YES
	Claims <u>1-5, 7-15, 41, 42, 46, and 47</u>	NO

2. Citations and explanations:

Claims 1-5, 7-15, 41, 42, 46, and 47 lack novelty under PCT Article 33(2) as being anticipated by Dietrich et al (US 6,309,858 B1). Dietrich et al. teach that SEQ ID NO:3 (column 27) is a polynucleotide fragment that is 86.9 percent homologous to SEQ ID NO:18 of the instant application. In addition, Dietrich et al. teach that SEQ ID NO:6 (column 51) is a polynucleotide fragment that is 88.2 percent homologous to SEQ ID NO:18 of the instant application.

Claims 1-5, 7-15, 41, 42, 46, and 47 lack novelty under PCT Article 33(2) as being anticipated by Mittman et al (2001). Mittman et al. teach that the polynucleotide with accession number AF129133 is a fragment that has a 92.1 percent homology to SEQ ID NO:18 of the instant application.

Claims 1-5, 7-15, 41, 42, 46, and 47 lack novelty under PCT Article 33(2) as being anticipated by Monteil et al., (2000). Monteil et al. teach that the polynucleotide with accession number AF211189 is a fragment that has a 88.2 percent homology to SEQ ID NO:18 of the instant application.

Claims 1-5, 7-15, 41, 42, 46, and 47 do not meet the criteria set out in PCT Article 33(4), and thus do not meet industrial applicability because the subject matter cannot be made or used in industry.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 1 is objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: it is unclear what is encompassed by degeneracy of the genetic code and biologically active fragments encoding a polypeptide capable of forming a functional T-type calcium channel.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-5, 7-15, 41, 42, 46, and 47 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claims 1-5, 7-15, 41, 42, 46, and 47 not fully supported by the description. The application, as originally filed, did not describe: biologically active fragments and homologues of the nucleic acid and amino acid sequences. Although the description provides support for the polynucleotide of SEQ ID NO:18, the description does not provide sufficient guidance for biologically active fragments or homologues of the nucleic acid or amino acid sequences.

Claims 1-5, 7-15, 41, 42, 46, and 47 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claims 1-5, 7-15, 41, 42, 46 and 47 are not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because: the description does not support biologically active fragments or homologues of a human T-type calcium channel subunit encoded by SEQ ID NO:18. The description also does not support fragments, derivatives, and variants of the nucleic acid molecule of SEQ ID NO: 18. The description also does not support the administration of any nucleic acid molecule or polypeptide, as required by claim 10.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of IPC:

A61K 8/18(2006.01);A61Q 13/00(2006.01);C12P 21/06(2006.01);C12N 15/00(2006.01),5/02(2006.01)